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Patent
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REMARKS

Claims 1, 5, and 6 have been amended to further clarify the invention. Claims 11 and 12 have been added.

The present invention addresses issues related to analyzing certain parts of the brain utilized during sleep such as the thalamus, putamen, and pons. The study of such parts of the brain is important because such parts of the brain have been linked to important bodily functions such as memory processing during sleeping. A better understanding of how these parts of the brain work could lead to a breakthrough in medical treatments and preventative care. However, the study of parts of the brain such as the thalamus, putamen, and pons have been inadequate because of difficulties such as poor time resolutions using a PET system and/or a heavy burden imposed on an examinee. The present invention remedies these problems by providing a better way to study parts of the brain. It results from a discovery that by comparing MRI information obtained from the brain while the brain is in a waking stage with MRI information obtained from the brain while the brain is in a sleeping stage, an analysis of parts of the brain such as the thalamus, putamen, and pons are now possible with better data and less burden on the examinee.

Examiner has rejected Claims 1, 5, and 6 under 35 U.S.C. §103(a) as being unpatentable over *Xiong et al.* (U.S. Pub. No. 2004/0096395 A1, hereinafter “*Xiong*”) in view of *Pettersson et al.* (U.S. 6,845,261 B2, hereinafter “*Pettersson*”).

Claims 1, 5, and 6 in relation to Xiong

Xiong is aimed at providing an improved combined spatio-temporal resolution of neural activity by directly detecting magnetic transients induced by neural firing. (See ¶ 0006, 0008). It is not aimed at solving the problem of analyzing parts of the brain related with sleeping while reducing the burden the examination has on the patient.

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In *Xlong* the patient is first immobilized "in a closely fitted, thermally molded, plastic facial mask individually formed for each subject" to "minimize head movement during MRI scanning." (See ¶ 0042). Stimulation can then be optionally provided and any neural activity is recorded by the MRI as activation information. (See ¶ 0029, 0042). The MRI images containing activation information could also be processed with software for image reconstruction, motion corrections, spatial normalization, value normalization, or statistical analyses to produce the desired msMRI image representing the activation information. (See ¶ 0030). Afterwards, the msMRI image representing the activation information is placed on top of T1-weighted MRI image acquired at the same location and orientation. (See ¶ 0047). Finally, the multiple msMRI images placed on top of T1-weighted MRI images can be visually compared in a chart. (See Fig. 5).

In contrast, the present invention seeks to solve the problem of analyzing activity with parts of the brain associated with sleeping such as thalamus, putamen, and pons. In the present invention, the patient is placed into an MRI system with a biosignal detection unit attached to him. Nearly simultaneously, the MRI system takes an MRI image while the biosignal detection means detects biosignals. The biosignal detection unit then sends both EEG and ECG signals to an event identification support unit. The event identifications support unit also receives a signal generated from the MRI system. The event identification unit then filters out from the EEG signal, the background noise which includes the ECG signal and the signal generated from the MRI system, to produce a filtered EEG signal. Then utilizing this filtered EEG signal, the event identification unit identifies which event is taking place, such as a waking stage, a sleeping stage 1, a sleeping stage 3, a sleeping stage 4, or stage REM. The event is then correlated with the MRI image. This process is repeated over a predetermined period of time. Then, an MRI image

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that is correlated with a waking stage is compared with an MRI image from a sleeping stage such as sleeping stage 4. In each MRI image the signal strength at each voxel is compared and the differential taken. The result is data that can be outputted into an image describing the activity of parts of the brain closely related to sleep activities such as the thalamus, pons, or putamen.

Unlike *Xiong*, the present invention does not require the immobilization of the patient. In the present invention, the patient does not have to be restrained and does not have to have a custom fitted support attached to him. This increases the comfort of the patient and also reduces costs.

Furthermore, *Xiong* utilizes stimulation while the present invention does not. The present invention does not utilize external stimulation to acquire data for its information. Thus, our invention is not hampered by the use of external stimulation.

Xiong also does not utilize biosignals to correlate the MRI images with certain body functions. More specifically, *Xiong* does not utilize biosignals to correlate the MRI images with specific body functions associated with waking and sleeping stages. This is important because without such correlation it would be difficult to study certain parts of the brain such as the thalamus, pons, or putamen.

Xiong teaches processing the data from an msMRI scan and then placing it on top of an MRI scan. This is different from the present invention because the data processing is only for single msMRI information instead of two msMRI information in conjunction with each other. Furthermore, the msMRI is only placed on top or overlaid on the MRI scan. The two images do not have the differential of the signal strengths of each voxel analyzed. Thus, *Xiong* does not teach nor suggest comparing the signal strength at each voxel from an MRI image where the patient is in a waking stage with the signal strength at each voxel from an MRI image where the

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patient is in a sleeping stage and taking the differential to form data that is relevant to the study of certain parts of the brain.

Thus Claims 1, 5, and 6 have novelty and inventiveness over *Xiong* and accordingly should be allowed.

Claims 1, 5, and 6 in relation to Petterson

Petterson seeks to solve a problem of correlating physiological data with MRI images. (See Col. 1, 48-61). It is not aimed at solving the problem of analyzing parts of the brain related with sleeping while reducing the burden the examination has on the patient.

In *Petterson*, the physiological data acquired is used as a trigger to initiate an MRI scan. MRI image is then correlated with the acquired physiological data. (See col. 1 ln. 64 – col. 2 ln. 17).

However, the present invention does not utilize the physiological data as a trigger. In contrast, the MRI image acquisition is not dependent on a certain physiological event happening. The MRI image is acquired nearly simultaneous with the physiological data so that the two may be correlated, but the MRI image acquisition does not happen only when a certain physiological even happens.

Furthermore, *Petterson* does not teach nor suggest comparing the signal strength at each voxel from an MRI image where the patient is in a waking stage with the signal strength at each voxel from an MRI image where the patient is in a sleeping stage and taking the differential to form data that is relevant to the study of certain parts of the brain.

Thus, Claims 1, 5, and 6 have novelty and inventiveness over *Petterson* and accordingly should be allowed.

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Claims 1, 5, and 6, in relation with *Xlong* in view of *Petterson*.

Xlong is aimed at providing an improved combined spatio-temporal resolution of neural activity by directly detecting magnetic transients induced by neural firing. (See ¶ 0006, 0008). *Petterson* is aimed at solving the problem of correlating physiological data with MRI images. (See Col. 1, 48-61). A person looking to solve the problem of improving the combined spatio-temporal resolution of neural activity would hardly look to an invention directed towards solving the problem of correlating physiological data with MRI images. There would be no need to correlate physiological data with the MRI images if the desire is to improve spatio-temporal resolution. Thus, there is no motivation to combine the two references.

"When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself"

Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985).

Even if the two references were combined, however improperly, the resulting hypothetical would be a spatio-temporal resolution of MRI images acquired by physiological triggers which required the patient to be immobilized.

The hypothetical combination would still be inadequate when compared to the present invention and dependent on a physiological trigger for MRI image acquisition. In contrast, the present invention would not be dependent on a physiological trigger for MRI image acquisitions. In addition, the patient must be immobilized and potentially stressed. In the present invention, however, the patient does not need to be immobilized.

The asserted rejection would only manipulate data for a single MRI image in isolation. In contrast, the present invention would compare the signal strength at each voxel from an MRI

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image with the signal strength at each voxel from another MRI image and take the differential. Furthermore, the present invention would not compare two random MRI images, but two specific ones. It would compare the signal strength at each voxel from an MRI image where the patient is in a waking stage with the signal strength at each voxel from an MRI image where the patient is in a sleeping stage and taking the differential to form data that is relevant to the study of certain parts of the brain. This is especially significant because by obtaining and comparing MRI data from a predetermined sleeping stage with MRI data from a predetermined waking stage and then taking the differential of the change in the MRI signal strength, the part of the brain that is functional can be determined.

Thus, Claims 1-10 and new Claims 11 and 12 have novelty and inventiveness over *Xlong* in view of *Pettersson* and accordingly should be allowed.

An early indication of allowance is respectfully requested.

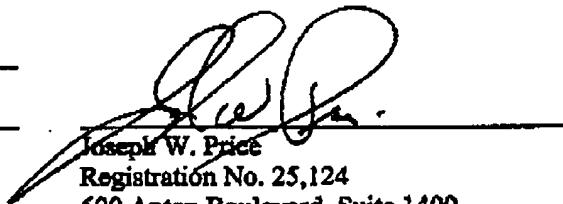
If the Examiner believes that a telephone interview will help further the prosecution of this case, he can contact the undersigned attorney at the listed telephone number.

I hereby certify that this correspondence is being transmitted via facsimile to the USPTO at 571-273-8300 on September 29, 2006.

Very truly yours,
SNELL & WILMER L.L.P.

By: Sharon Farnum
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